

1. A composition for local administration of an anti-tumor chemotherapeutic to a patient having a tumor, the composition comprising;

2. The composition of claim 1, wherein the anti-tumor chemotherapeutic is in a formulation comprising a mixture of the anti-tumor chemotherapeutic and a plasma protein in an amount effective to solubilize the anti-tumor chemotherapeutic.

4. The composition of claim 2, wherein the longest diameter of the microspheres is less than about 20 microns.

6. The composition of claim 2, wherein the anti-tumor chemotherapeutic is contained within the microsphere.

7. The composition of claim 2, wherein the anti-tumor chemotherapeutic is attached to the microsphere.

8. The composition of claim 2, wherein the microspheres comprises a biodegradable polymer.

9. The composition of claim 8, wherein the biodegradable polymer is selected from the group consisting of polyacetic acid, polyglycolic acid and a co-polymer of polyglycolic and polyacetic acid.

10. The composition of claim 2, wherein the ~~the~~ microspheres comprise a non-biodegradable

12

polymer.

11. The composition of claim 13 wherein, the non-biodegradable polymer is an ethylene-vinyl acetate copolymer.

12. The composition of claim 2, wherein degradation of the microspheres releases the anti-tumor chemotherapeutic from the microspheres in a therapeutically effective amount.

13. The composition of claim 12, wherein up to about 50 % of the anti-tumor chemotherapeutic is released from the microspheres within about 24 hours after administration of the microspheres to the patient.

14. The composition of claim 12, wherein between about 15 to about 25 % of the anti-tumor chemotherapeutic is released from the microspheres within about 24 hours after administration of the microspheres to the patient.

15. The composition of claim 2, wherein the anti-tumor chemotherapeutic is released from the microsphere by diffusion.

16. The composition of claim 15, wherein the anti-tumor chemotherapeutic is released in a therapeutically effective amount over a period of time from about 1 week to about six months after administration to the patient.

17. The composition of claim 15, wherein the anti-tumor chemotherapeutic is released in a therapeutically effective amount over a period of time from about 3 weeks to about 2 months after administration to the patient.

18. The composition of claim 2, wherein the anti-tumor chemotherapeutic is an apoptosis inducing chemotherapeutic.

19. The composition of claim 18, wherein the apoptosis inducing chemotherapeutic is selected from the group consisting of cisplatin, adriamycin, butyric acid,

cyclophosphamide, etoposide, amsacrine, genistein, and mitoguazone.

20. The composition of claim 18, wherein the anti-tumor chemotherapeutic is paclitaxel.

21. The composition of claim 20, wherein the paclitaxel is at a concentration from about 0.1 to about 10 mg/mL.

22. The composition of claim 20, wherein the paclitaxel is at a concentration from about 0.5 to about 5 mg/mL.

23. The composition of claim 2, wherein the suspending solution also includes an apoptosis inducing chemotherapeutic.

24. The composition of claim 23, wherein the apoptosis inducing chemotherapeutic is paclitaxel.

25. The composition of claim 24, wherein the paclitaxel in both the microspheres and in the solution is about 70 to about 280 mg.

26. The composition of claim 24, wherein the paclitaxel in both the microspheres and in the solution is at a concentration of about 135 mg/m<sup>2</sup> to about 175 mg/m<sup>2</sup>.

27. The composition of claim 23, wherein between about 10 % to about 90 % of the paclitaxel is present in the microspheres.

28. The composition of claim 23, wherein between about 60 % to about 90 % of the paclitaxel is present in the microspheres.

29. The composition of claim 23, wherein between about 80 % to about 90 % of the paclitaxel is present in the microspheres.

30. The composition of claim 2, further comprising a second anti-tumor chemotherapeutic in the suspending solution.

31. The composition of claim 30, wherein the second anti-tumor chemotherapeutic is an apoptosis inducing chemotherapeutic.

32. The composition of claim 30, wherein the second anti-tumor chemotherapeutic is selected from the group consisting of paclitaxel, cisplatin, adriamycin, butyric acid, cyclophosphamide, etoposide, amsacrine, genistein, and mitoguazone.
33. A method for local administration of an anti-tumor chemotherapeutic to a tumor, comprising the steps of:
- delivering a chemotherapeutic reservoir to the tumor; and,
- releasing the chemotherapeutic from the reservoir to an interstitial space of the tumor in a therapeutically effective amount,
- wherein, the chemotherapeutic reservoir includes a plurality of microspheres incorporating the anti-tumor chemotherapeutic and a suspending solution surrounding the microspheres.
34. The method of claim 33, wherein the chemotherapeutic reservoir comprises a mixture of the anti-tumor chemotherapeutic and a plasma protein in an amount effective to solubilize the anti-tumor chemotherapeutic.
35. The method of claim 34, wherein the plasma protein is selected from the group consisting of human serum albumin and  $\gamma$ -immunoglobulin.
36. The method of claim 34, wherein the microspheres comprise a biodegradable polymer.
37. The method of claim 36, wherein the biodegradable polymer is selected from the group consisting of polyacetic acid, polyglycolic acid and a co-polymer of polyglycolic and polyacetic acid.
38. The method of claim 34, wherein the microspheres comprise a non-biodegradable polymer.
39. The method of claim 38, wherein the non-biodegradable polymer is a ethylene-vinyl

acetate copolymer.

40. The method of claim 34, wherein the anti-tumor agent is released from the microspheres in a therapeutically effective amount by degradation of the microspheres.
41. The method of claim 40, wherein about 50 % of the anti-tumor chemotherapeutic from the microspheres within about 24 hours following delivery of the chemotherapeutic reservoir to the tumor.
42. The method of claim 40, wherein about 15 to about 25 % of the anti-tumor chemotherapeutic from the microspheres within about 24 hours following delivery of the chemotherapeutic reservoir to the tumor.
43. The method of claim 34, wherein the anti-tumor chemotherapeutic is released from the microsphere by diffusion.
44. The method of claim 43, wherein the anti-tumor chemotherapeutic is continuously released from the microspheres in a therapeutically effective amount for a time period lasting from between about one week to about six months.
45. The method of claim 43, wherein the anti-tumor chemotherapeutic is continuously released from the microspheres in a therapeutically effective amount for a time period lasting from between about three weeks to about two months.
46. The method of claim 34, wherein the longest diameter of the microspheres are less than about 20 microns.
47. The method of claim 34, wherein the microspheres are microcapsules.
48. The method of claim 34, wherein the anti-tumor chemotherapeutic is an apoptosis inducing chemotherapeutic.
49. The method of claim 48, wherein the apoptosis inducing chemotherapeutic is selected

from the group consisting of cisplatin, adriamycin, butyric acid, cyclophosphamide, etoposide, amsacrine, genistein, and mitoguazone.

50. The method of claim 48, wherein the anti-tumor chemotherapeutic is paclitaxel.

51. The composition of claim 50, wherein the paclitaxel is at a concentration from about 0.1 to about 10 mg/mL.

52. The method of claim 50, wherein the paclitaxel is at a concentration from about 0.5 to about 5 mg/mL.

53. The method of claim 34, wherein the suspending solution also includes an apoptosis inducing chemotherapeutic.

54. The method of claim 53, wherein the apoptosis inducing chemotherapeutic is paclitaxel.

55. The method of claim 53, wherein the total paclitaxel in both the microspheres and in the solution is about 70 to about 280 mg.

56. The method of claim 53, wherein the total paclitaxel in both the microspheres and in the solution is at a concentration of about 135 mg/m<sup>2</sup> to about 175 mg/m<sup>2</sup>.

57. The method of claim 53, wherein between about 10 % to about 90 % of the paclitaxel is present in the microspheres.

58. The method of claim 53, wherein between about 60 % to about 90 % of the paclitaxel is present in the microspheres.

59. The method of claim 53, wherein between about 80 % to about 90 % of the paclitaxel is present in the microspheres.

60. The method of claim 34, further comprising a second anti-tumor chemotherapeutic in the suspending solution.

61. The method of claim 60, wherein the second anti-tumor chemotherapeutic is an

apoptosis inducing <sup>125</sup>chemotherapeutic.

62. The method of claim 60, wherein the second anti-tumor chemotherapeutic is selected from the group consisting of paclitaxel, cisplatin, adriamycin, butyric acid, cyclophosphamide, etoposide, amsacrine, genistein, and mitoguazone.
- 5 63. The method of claim 34, wherein the delivering step includes the step of positioning the chemotherapeutic reservoir within the tumor.
64. The method of claim 34, wherein the delivering step includes the step of intratumorally injecting the chemotherapeutic reservoir within the tumor.
65. The method of claim 34, wherein the delivering step includes the step of positioning chemotherapeutic reservoir adjacent to the tumor.